Version with Markings to Show Changes Made

Kindly add the new claims as follows:

--53. (New) An assay device comprising:

at least one chamber in fluid connection with at least one pathway, said at least one pathway being adapted to allow fluid to flow to/from said at least one chamber; and

means for selectively applying heat to at least one volume of a reversibly, thermally deformable material;

wherein there is provided said at least one volume of said reversibly, thermally deformable material in said at least one pathway which, in use, changes its state so as to cause a change of a rate of fluid flow along said at least one pathway.

54. (New) An assay device comprising:

at least one chamber in fluid connection with at least one pathway, said at least one pathway being adapted to allow fluid to flow to/from said at least one chamber; and

means for selectively applying heat to at least one volume of reversibly, thermally deformable material;

wherein there is provided at least one recess located substantially adjacent said at least one pathway and, situated in said at least one recess, there is provided said at least one volume of said reversibly, thermally deformable material which, in use, changes its state so as to cause a change of a rate of fluid flow along said at least one pathway.

55. (New) The assay device according to claim 53, wherein:

there is at least one recess located substantially adjacent said at least one pathway.

56. (New) The assay device according to claim 54, wherein:

an opening is provided, said opening acting as a vent to or from said at least one recess.

57. (New) The assay device according to claim 53, wherein:

said at least one volume of said reversibly, thermally deformable material is situated in said at least one pathway such that said at least one pathway is partially obstructed.

58. (New) The assay device according to claim 53, wherein:

said at least one chamber includes a deformable envelope and at least two points of said envelope are connected by way of said at least one volume of said reversibly, thermally deformable material.

59. (New) The assay device according to claim 53, wherein:

a region of said assay device has at least one hydrophobic portion so that a flow of said at least one volume of said reversibly, thermally deformable material is guided along a predetermined path.

60. (New) The assay device according to claim 53, wherein:

at least one surface defined by or in said assay device is resiliently deformable.

61. (New) The assay device according to claim 53, wherein:

a plurality of volumes of said reversibly deformable material are provided, each volume being accessible independently one from another.

62. (New) The assay device according to claim 61, wherein:

each volume of said plurality of volumes of said reversibly, thermally deformable material is accessible independently and sequentially one from another.

63. (New) The assay device according to claim 53, further comprising:

at least one of an inlet port, a reaction chamber, a waste depot, a filter chamber, an infinity capture and processing chamber, a wash solution/reagent reservoir, an array of metered readout cells and a breather tube.

64. (New) The assay device according to claim 53, further comprising:

means for selectively removing heat from said at least one volume of said reversibly, thermally deformable material.

65. (New) The assay device according to claim 53, further comprising:

means for selectively applying pressure to at least one region contained within said assay device.

66. (New) An assay device comprising:

at least one chamber in fluid connection with at least one pathway, said at least one pathway being adapted to allow fluid to flow to/from said at least one chamber;

at least one volume of a reversibly, thermally deformable material situated in said at least one pathway which, in use, changes its state so as to cause a change of a rate of fluid flow along said at least one pathway;

at least one hydrophobic portion which defines a path along which said at least one volume of said reversibly, thermally deformable material is guided; and

means for selectively applying heat to said at least one volume of said reversibly, thermally deformable material.

67. (New) An assay device including:

at least one chamber in fluid connection with at least one pathway, said at least one pathway being adapted to allow fluid to flow to/from said at least one chamber;

at least one recess located substantially adjacent said at least one pathway;

at least one volume of a reversibly, thermally deformable material situated in said at least one recess which, in use, changes its state so as to cause a change of a rate of fluid flow along said at least one pathway;

at least one hydrophobic portion which defines a reversibly, thermally deformable material path along which said reversibly, thermally deformable material is guided; and

means for selectively applying heat to said at least one volume of said reversibly, thermally deformable material.

68. (New) An apparatus for varying a rate of fluid flow along at least one pathway, the apparatus comprising:

said at least one pathway and at least one volume of a reversibly, thermally deformable material disposed within said at least one pathway whereby, in use, a change of state of said at least one volume of said reversibly, thermally deformable material causes a change of said rate of fluid flow along said at least one pathway; and

means for selectively applying heat to said at least one volume of said reversibly, thermally deformable material.

69. (New) Apparatus for varying a rate of fluid flow along at least one pathway, said apparatus comprising:

said at least one pathway and at least one volume of a reversibly, thermally deformable material disposed adjacent said at least one pathway whereby, in use, a change of state of said at least one volume of said reversibly, thermally deformable material causes a change of said rate of fluid flow along said at least one pathway; and

means for selectively applying heat to said at least one volume of said reversibly, thermally deformable material.

70. (New) Apparatus according to claim 68, further comprising:

at least one chamber in fluid connection with said at least one pathway.

71. (New) Apparatus according to claim 70, wherein:

said at least one volume of said reversibly, thermally deformable material is disposed within said at least one chamber.

72. (New) Apparatus according to any claim 68, further comprising:

at least one recess capable of receiving said reversibly, thermally deformable material located substantially adjacent said at least one pathway.

73. (New) Apparatus according to claim 72, wherein:

said at least one recess has an opening which acts as a vent in order to permit a flow of gas therethrough.

74. (New) Apparatus according to claim 68, further comprising:

means for removing heat from said apparatus in order to increase or decrease a rate of said change of state of said reversibly, thermally deformable material.

75. (New) Apparatus according to claim 68, further comprising:

means for supplying at least one of pressure, uv radiation, light and ultrasonic energy to said apparatus in order to increase or decrease a rate of said change of state of said reversibly, thermally deformable material.

76. (New) Apparatus according to claim 68, wherein:

said reversibly, thermally deformable material includes a polymer.

77. (New) Apparatus according to claim 68, wherein:

said reversibly, thermally deformable material includes polypropylene polystyrene.

78. (New) Apparatus according to claim 68, further comprising:

at least one hydrophobic portion which defines a reversibly, thermally deformable material path along which the said reversibly, thermally deformable material is guided.

79. (New) A method of varying a rate of fluid flow along at least one pathway comprising the steps of:

providing at least one recess substantially adjacent said at least one pathway;

locating at least one volume of a reversibly, thermally deformable material in said at least one recess; and

changing a state of said reversibly, thermally deformable material by application of heat so that at least a portion of said reversibly, thermally deformable material passes into said at least one pathway thereby substantially restricting flow of said fluid along said at least one pathway.

80. (New) A method according to claim 79, wherein:

said at least a portion of said reversibly, thermally deformable material passes into said at least one pathway along a predetermined path.

81. (New) A method of varying a rate of fluid flow along at least one pathway comprising the steps of:

providing said at least one pathway;

locating at least one volume of a reversibly deformable material in said at least one pathway so that said reversibly deformable material substantially restricts said flow of fluid along said at least one pathway; and

changing a state of said reversibly deformable material by application of heat so that at least a portion of said reversibly deformable material passes along a predetermined path, thereby permitting flow of said fluid along said pathway.

82. (New) A method of varying a rate of fluid flow along at least one pathway comprising the steps of:

providing said at least one pathway;

locating at least one volume of a reversibly deformable material in said at least one pathway so that said reversibly deformable material substantially permits said flow of fluid along said at least one pathway; and

changing a state of said reversibly deformable material by application of heat so that at least a portion of said reversibly deformable material passes along a predetermined path, thereby substantially restricting flow of said fluid along said at least one pathway.

83. (New) The method according to claim 80, wherein:

said predetermined path is defined by one or more hydrophobic regions.

84. (New) The method according to claim 79, wherein:

said change of state of said reversibly deformable material is further controlled by applying to said reversibly deformable material at last one of pressure, uv radiation, light and ultrasonic energy.

REMARKS

Claims 1-48 are canceled herein. Claims 53-84 are added herein. Claims 53-84 remain pending in the application.

The Applicant respectfully requests the Examiner to reconsider earlier rejections in light of the following remarks. No new issues are raised nor is further search required as a result of the changes made herein. Entry of the Amendment is respectfully requested.

Claims 1-8, 10-33 and 36-48 over Burns

In the Office Action, claims 1-8, 10-33 and 36-48 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Burns et al., U.S. Patent No. 6,379,929 ("Burns"). The Applicant respectfully traverses the rejection.

Claims 1-8, 10-33 and 36-48 have been canceled herein, making the rejections of claims 1-8, 10-33 and 36-48 now moot. Claims 53-84 have been added herein.

Claims 53-84 recite, inter alia, changing fluid flow along a pathway by changing a state of a reversibly deformable material through application of heat.

Burns appears to disclose an isothermal amplification of nucleic acids, such as DNA and RNA, in a microfabricated structure. By necessity such amplification reactions occur at temperatures that fluctuate only to a very tiny degree and are therefore distinguished from, inter alia, the polymerase chain reaction. The microfabricated structure for maintaining such a constant temperature environment comprises silicon, glass or quartz components including channels and reaction chambers.

Burns discloses a microfabricated structure for maintaining a constant temperature of channels and reaction chambers. The microfabricated structure is comprised of silicon, glass or quartz components **NOT** a reversibly deformable material. Burns fails to disclose a reversibly deformable material, much less disclose changing fluid flow along a pathway by changing a state of a

reversibly deformable material through application of heat, as recited by claims 53-84.

A benefit of using a heat controlled reversibly deformable material to change fluid flow in a pathway is, e.g., a precise flow rate and volumetric control of a fluid in an apparatus. Precise flow rates and volumetric control of a fluid is vital in any commercial or laboratory scale process where a volume of liquid in a pathway has to be presented under specific conditions at a final or intermediate position in a pathway. Enhancing the flexibility of an apparatus or process represents a worthwhile technical achievement.

Accordingly, for at least all the above reasons, claims 53-84 are patentable over the prior art of record. It is therefore respectfully requested that the rejection be withdrawn.

Claims 1-7, 12, 18-31, 34-43 and 45-58 over Gubinski

In the Office Action, claims 1-7, 12, 18-31, 34, 36-43 and 45-58 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Gubinski et al., U.S. Patent No. 5,278,079 ("Gubinski"), with claim 35 rejected under 35 U.S.C. §103(a) as allegedly being obvious over Gubinski. The Applicant respectfully traverses the rejection.

Claims 1-7, 12, 18-31, 34-43 and 45-58 have been canceled herein, making the rejections of claims 1-7, 12, 18-31, 34-43 and 45-58 now moot. Claims 53-84 have been added herein.

Claims 53-84 recite, *inter alia*, changing fluid flow along a pathway by changing a state of a reversibly deformable material through application of heat.

Gubinski appears to teach a method and apparatus for sealing a device such that fluid can no longer pass through it. A polymer that expands on contact with water is positioned in a portion of a tube that has a smaller diameter than that of the majority of the tube. When water is introduced into the tube, the polymer increases in volume to completely fill the lower diameter section, thus preventing water from exiting.

Gubinski relates specifically to the field of medical diagnostics where small volumes of liquid such as blood and saliva are involved. It is of paramount importance that a polymer expands quickly and completely to seal the device being used and prevent even fractional loss of liquid. Gubinski fails to disclose use a material used to control fluid flow, much less disclose changing fluid flow along a pathway by changing a state of a reversibly deformable material through application of heat, as recited by claims 53-84.

Accordingly, for at least all the above reasons, claims 53-84 are patentable over the prior art of record. It is therefore respectfully requested that the rejection be withdrawn.

Claims 9, 34 and 35 over Burns in view of Jones

In the Office Action, claims 9, 34 and 35 were rejected under 35 U.S.C. §103(a) as allegedly being obvious over Burns in view of Jones U.S. Patent No. 5,267,585 ("Jones"). The Applicant respectfully traverses the rejection.

Claims 9, 34 and 35 have been canceled herein, making the rejections of claims 9, 34 and 35 now moot. Claims 53-84 have been added herein.

Claims 53-84 recite, *inter alia*, changing fluid flow along a pathway by changing a state of a reversibly deformable material through application of heat.

As discussed above, Burns fails to disclose changing fluid flow along a pathway by changing a state of a reversibly deformable material through application of heat, as recited by claims 53-84.

The Office Action relies on Jones to allegedly make up for the deficiencies in Burns to arrive at the claimed invention. The Applicant respectfully disagrees.

Jones appears to disclose a method and device for controlling fluid flow along a pathway that is provided between an inlet and outlet by a channel within a regulating chamber. An elastomeric element is provided within the

channel that is deformable, the extent of this deformation controlling the rate of liquid flow in the channel.

Jones discloses an elastomeric element that controls fluid flow along a pathway. Deformation of the elstomeric element is controlled by a valve spindle state, NOT by heat. Jones fails to disclose changing fluid flow along a pathway by changing a state of a reversibly deformable material through application of heat, as recited by claims 53-84.

Neither Burns nor Jones, either alone or in combination, disclose, teach or suggest changing fluid flow along a pathway by changing a state of a reversibly deformable material through application of heat, as recited by claims 53-84.

Accordingly, for at least all the above reasons, claims 53-84 are patentable over the prior art of record. It is therefore respectfully requested that the rejection be withdrawn.

Claim 9 over Gubinski in view of Jones

In the Office Action, claim 9 was rejected under 35 U.S.C. §103(a) as allegedly being obvious over Gubinski in view of Jones. The Applicant respectfully traverses the rejection.

Claim 9 has been canceled herein, making the rejection of claim 9 now moot. Claims 53-84 have been added herein.

Claims 53-84 recite, *inter alia*, changing fluid flow along a pathway by changing a state of a reversibly deformable material through application of heat.

As discussed above, Gubinski fails to disclose, teach or suggest changing fluid flow along a pathway by changing a state of a reversibly deformable material through application of heat, as recited by claims 53-84.

As discussed above, Jones fails to disclose, teach or suggest changing fluid flow along a pathway by changing a state of a reversibly deformable material through application of heat, as recited by claims 53-84.

Neither Gubinski nor Jones, either alone or in combination, disclose, teach or suggest changing fluid flow along a pathway by changing a

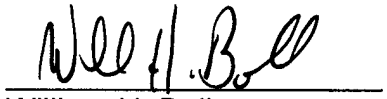
state of a reversibly deformable material through application of heat, as recited by claims 53-84.

Accordingly, for at least all the above reasons, claims 53-84 are patentable over the prior art of record. It is therefore respectfully requested that the rejection be withdrawn.

Conclusion

All objections and rejections having been addressed, it is respectfully submitted that the subject application is in condition for allowance and a Notice to that effect is earnestly solicited.

Respectfully submitted,



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